TORNIER

K130051 (1/4)

JUL 1 5 2013

510(K) Summary

Summary of Safety and Effectiveness information
510(k) Premarket Notification – 611 Ankle Fusion Nail

Date prepared: January 2nd, 2012

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) Device name

Trade name: **611 Ankle Fusion Nail**
Common name: Ankle Arthrodesis Nail
Classification name: 888.3020 Fixation, Intramedullary and Accessories

2) Submitter

Tornier SAS
161 Rue Lavoisier
38330 Montbonnot Saint Martin - France

3) Applicant

Tornier SAS
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4) Company contact

Tornier SAS
Mr Damien Guillaud
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5) Classification

Device class: Class II
Classification panel: Orthopedic
Product code: HSB

6) Equivalent Predicate devices

T2 Ankle Arthrodesis Nail, HOWMEDICA OSTEONICS CORP (now STRYKER), K051590.
Synthes Hindfoot Arthrodesis Nail System, SYNTHES (USA), K051678.

7) Device description

The *611 Ankle Fusion Nail* consists of an Ankle nail associated with locking screws as well as a plug. The Ankle nails are available in variety of diameters and angulations. The plug screwed into the threaded end of the nail is to prevent bone ingrowth. The locking screws are self-tapping screws.

All components of the *611 Ankle Fusion Nail* are single use devices. The Ankle nail and plug are delivered sterile. The locking screws are delivered non sterile with the instrumentation.

8) Materials

The nail, the locking screws and the plug are made out of titanium alloy (Ti6Al4V) according to ISO 5832-3.

9) Intended Use

The *611 Ankle Fusion Nail* is intended to immobilize tibiotalar and subtalar joints of the ankle in order to obtain the fusion of these joints and to decrease pain as compared to the preoperative condition.

10) Indications For Use

The immobilization of the ankle with the *611 Ankle Fusion Nail* is indicated in the following cases:

- Severe defects of the ankle and subtalar joints and/or deformations with/without instability,
- Avascular necrosis of the talus,
- Traumatic or post-traumatic involvement of the ankle and subtalar joints,
- Degenerative pathologies: primary or post-trauma osteoarthritis, rheumatoid polyarthritis.
- Revision of the arthrodesis or revision of the total ankle prosthesis,
- Neuroarthropathy or neuropathic deformation of the ankle/Charcot Foot.

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11) Summary of technological characteristics

Main features or system characteristics		611 Ankle Fusion Nail	T2 Ankle Arthrodesis Nail	Synthes Hindfoot Arthrodesis Nail System
Manufacturer		Tornier	Howmedica Osteonics Corp	Synthes (USA)
K-number		pending	K051590	K051678
Materials	nail	Titanium alloy	Titanium alloy	Titanium alloy
	screws	Titanium alloy	Titanium alloy	Titanium alloy
	plug	Titanium alloy	Titanium alloy	Titanium alloy
Sizes	nail	Length (mm): 180 Curvature : 6° / 11° valgus Left & right Proximal diameters : Ø10, Ø12 Distal diameters : Ø12, Ø13	Lengths (mm): 150 / 200 / 300 Curvature : 5° valgus Left & right Proximal diameters : Ø10, Ø11, Ø12 Distal diameters : Ø12	Lengths (mm): 150 / 180 / 240 Curvature : 12° valgus Left & right Proximal diameters : Ø10, Ø12, Ø13 Distal diameters : Ø10, Ø12,5, Ø13
	Screws: dia.(mm) / Lengths	5 / 20 to 100	5 / 25 to 120	5, 6 / 26 to 125
	Plug - Thickness (mm):	4 sizes (0, 2.5, 5, 7.5)	4 sizes (0; 5, 10, 15)	1 size (0)
Screw positioning		- 2 tibial - 2 talo-calca	- 2 tibial - 2 calca - 1 talar	- 2 tibial - 2 calca - 1 talar
Intended use		tibiotalocalcaneal arthrodesis	tibiotalocalcaneal arthrodesis	tibiotalocalcaneal arthrodesis
Method of fixation		cementless	cementless	cementless
Terminal sterilization		Gamma	Gamma	Gamma

The indications for use, the technical characteristics (materials, manufacturing principle and method of fixation), the packaging and the sterilization process of the *611 Ankle Fusion Nail* are identical or equivalent to the predicate devices.

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12) Non-clinical testing

Non-clinical testing were performed on the *611 Ankle Fusion Nail* to assess that no new safety and efficiency issues were raised with this device.

The following test was performed:

- Fatigue testing.

The results of those evaluations allow us to conclude that the proposed *611 Ankle Fusion Nail* described in this submission does not induce any new or higher risk compared to the predicate devices and therefore both devices (proposed and predicate) are substantially equivalent.

13) Substantial equivalence conclusion

Substantial equivalence of the new *611 Ankle Fusion Nail* to the cleared predicates can be demonstrated on the following grounds, according to the FDA's Guidelines for Substantial Equivalence Decision Making Process:

- The *611 Ankle Fusion Nail* is compared to the predicate devices.
- The *611 Ankle Fusion Nail* has the same intended use as the cleared predicates and has very similar indications for use.
- Major technological characteristics are equivalent between the *611 Ankle Fusion Nail* and the predicate devices:
  - Equivalence of general features,
  - Equivalent technological features: materials,
  - Equivalent biomechanical features: mechanical characteristics,
  - Equivalent means of fixation,
  - Equivalent prosthetic dimensions,
  - Equivalent surgical technique.

Therefore, in light of the above information, the company believes that the *611 Ankle Fusion Nail* may be cleared via the 510(k) notification process for use as an ankle arthrodesis nail.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 15, 2013

Tornier SAS
% Mr. Damien Guillaud
Regulatory Affairs Specialist
161 Rue Lavoisier
38334 Montbonnot Cedex
France

Re: K130051
Trade/Device Name: 611 Ankle Fusion Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: April 10, 2013
Received: April 18, 2013

Dear Mr. Guillaud:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: *611 Ankle Fusion Nail*

Intended use:

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Indications For Use:

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- Revision of the arthrodesis or revision of the total ankle prosthesis,
- Neuroarthropathy or neuropathic deformation of the ankle/Charcot Foot.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices